

REMARKS

Claims 12-23 are pending in the application; each of the claims has been rejected.

Amendment of claim 12 to recite “at least one fiber” finds support in the specification, such as in paragraph 0032 of the published application.

New claim 24 finds support in claim 23. Amendment of claim 12 to recite a new concentration of bacterial strains, and new claims 25 and 26, find support in paragraph 0027 of the published application. The remainder of the amendments simply serves to place the claims more fully in U.S. claim format and to correct obvious misspellings.

No new matter has been added. Entry of the Amendment is respectfully requested.

I. Information Disclosure Statement

Applicants thank the Examiner for return of an acknowledged copy of the document list submitted with the Information Disclosure Statement filed in the instant application on October 31, 2006. However, Applicants note that the PCT publication listed near the top of the list was not acknowledged. Applicants therefore respectfully request return of a copy of the document list where each of the listed documents is acknowledged.

II. Claim Rejections Under 35 U.S.C. §112

At page 3 of the Office Action, claims 12-23 have been rejected as being non-enabled under 35 U.S.C. §112, first paragraph.

The Examiner states that while a method of *treating* a stress-induced inflammatory disorder is enabled, a method for *preventing* such a disorder is not enabled.

Included herewith is an amendment to the claims such that recitation of methods for preventing a stress-induced inflammatory disorder has been canceled from the claims. As the Examiner has indicated that a method for treating such disorders is fully enabled,

the claims are now enabled as amended and Applicants respectfully request reconsideration and withdrawal of this rejection.

III. Claim Rejections Under 35 U.S.C. §103

At page 7 of the Office Action, claims 12-23 have been rejected as being obvious under 35 U.S.C. §103 over Monte (US 2003/0147857) in view of Kruszewskya et al. (*Microecol. Therapy*, 2002), Kaur et al. (*Eur. J. Pharma. Sci.*, 2002) and Zhang et al. (*JBC*, 2002).

The Examiner has maintained the rejection of claims 12-23 on the basis that the combination of the four cited documents makes the subject matter of the pending claims obvious. Applicants respectfully traverse the Examiner's position for the following reasons.

Applicants note that as the basis of the rejection the Examiner appears to be selecting random lactic acid bacteria disclosed in one document (Kruszewskya) to be used in a method taught in another document (Monte) and arguing that such a method would have the inherent activity disclosed in further documents (Kaur; Zhang).

In order for the Examiner to maintain a rejection under 35 U.S.C. §103, the Examiner must show (i) that the claimed invention is merely the predictable use of known elements according to their established functions, and (ii) that there was an apparent reason to combine the known elements in the manner being claimed. *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (2007).

Applicants contend that the Examiner has not established either element of the test set forth in *KSR*. Firstly, the Examiner has not established the claimed invention is merely the predictable use of known elements according to their established functions. The Examiner suggests that it would have been obvious to use some of the lactic acid bacteria disclosed Kruszewskya in the method of Monte. However, as Applicants have previously pointed out, there is nothing in Kruszewskya to suggest that a formulation of four specific bacteria strains could be successfully used in the method of Monte, let alone

used to produce the therapeutic effects recited in the pending claims. That is, there is no teaching or suggestion in any of the art cited by the Examiner that would suggest that the use of the claimed bacteria in a therapeutic formulation would have been a “predictable use” to the skilled artisan.

A close reading of Kruszewskya reveals that it does not teach or suggest any beneficial properties stemming from the use of a formulation of all four of the noted strains. While Kruszewskya discloses each of the four strains recited in the claims, it also teaches several others strains. Importantly, each of the strains disclosed in Kruszewskya was tested individually to determine their characteristics. (Kruszewskya, p. 43). Kruszewskya does not teach or suggest utilizing any of these strains in combination. Nor does Kruszewskya teach or suggest utilizing any of these strains in a formulation with at least one fiber. Thus Kruszewskya does not teach the predictable use of known elements. In the absence of experimental data there would be no means to know *a priori* whether a formulation comprising a combination of four strains of Kruszewskya would have a therapeutic effect.

Indeed, Kruszewskya teaches away from the present invention. Kruszewskya recites that: “[t]here is also an increasing interest to add selected strains to food items to prevent or to treat various diseases, such as infections, allergy, inflammatory bowel disease and cancer.” However, Kruszewskya specifically concludes that “[o]ften the health claims on commercial products have been based on insufficient *in vitro* and *in vivo* data.” (Kruszewskya, p. 43). Kruszewskya further concludes that its own tests do not conclusively show that the strains tested therein are effective to treat any specific diseases. (Kruszewskya, p. 45). The inconclusive results of Kruszewskya do not teach the predictable use of known elements according to their established functions.

Secondly, the Examiner has also not established an apparent reason to combine the known elements in the manner being claimed. There must be some motivation or direction to select the particular bacterial strains recited in the claims from those provided in the cited art. The Examiner has not pointed to such motivation or direction, nor is such

motivation apparent in the cited art. As discussed in the Amendment filed by Applicants on April 25, 2008, the cited references do not teach or suggest a formulation comprising each of the specific bacterial strains (*Pediococcus pentosaceus* 16:1 (LMG P-20608), *Leuconostoc mesenteriodes* 23-77:1 (LMG P-20607), *Lactobacillus paracasei subsp paracasei* F-19 (LMG P-17086), and *Lactobacillus plantarum* 2362 (LMG P-20606)). Indeed, the Examiner concedes in the Office Action that Monte does not teach or suggest the utilization of *Leuconostoc mesenteriodes* 23-77:1 (LMG P-20607), *L. Paracasei subsp paracasei* F-19 (LMG P-17086), or *L. plantarum* 2362 (LMG P-20606). (Office Action, p. 8).

Monte does list some species of lactic acid bacteria, without reference to specific strains, in a laundry list of numerous unspecified bacteria and discloses that one or more of these probiotics could be utilized to form a prebiotic or probiotic composition. (Monte, para. 25). However, Monte does not recite the specific bacterial strains or the specific combination of the four strains recited in the pending claims. Therefore, formulations comprising one or more of the laundry list of possible probiotics as disclosed in Monte do not teach or suggest the formulation comprising the four specific strains recited in the pending claims. None of the cited references teaches or suggests a formulation comprising the four specific bacterial strains recited in the pending claims.

The Examiner asserts that Kruszewskya teaches each of the four strains recited in the pending claims. (Office Action, p. 8). However, as discussed above while Kruszewskya discloses each of the noted strains, it does not teach or suggest a formulation comprising all four of the strains as recited in the pending claims. Nor does any of the other cited references disclose a formulation of four specific bacterial strains with at least one fiber as recited in the pending claims.

On a further point, Applicants also note that according to the Examiner, the motivation to combine the strains of Kruszewskya with the method of Monte would be the production of anti-inflammatory cytokines and anti-oxidants of the strains disclosed by Kruszewskya. However, it is important to note that Kruszewskya is silent as to any

possible anti-inflammatory effects of *L. mesenteroides* 23-77:l. Furthermore, there are no data supporting such an effect in Kruszewskya. Therefore the skilled person would not have been motivated to include this strain in the formulation of claim 12.

Moreover, it should be noted once again that the only conclusion the skilled person could draw from Kruszewskya is that *L. paracasei subsp. paracasei* F-19 would provide pro-inflammatory effects and not anti-inflammatory effects. The production of the pro-inflammatory cytokine IL-8 by this organism was much higher than the production of the anti-inflammatory cytokine IL-10. (Kruszewskya, Table 3). Accordingly, the skilled person would not even consider including *L. paracasei subsp. paracasei* F-19 in a formulation to be used to treat stress-induced inflammatory disorder in a mammal. The skilled artisan would instead be discouraged from the combination suggested by the Examiner.

In view of each of these points, the Examiner has failed to establish that the cited references teach or suggest the claims as amended. Accordingly, in view of the forgoing differences, the claims are non-obvious and Applicants respectfully request reconsideration and withdrawal of this rejection.

IV. Conclusion

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

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